

### **REMARKS/ARGUMENTS**

The foregoing amendments have been made with a view to continued prosecution. Claim 1 has been amended to define the characteristics of the originally claimed elastic tubular lattice. The claimed self-expandable stent is distinguishable from a stent in which expansion occurs from plastic deformation. As more clearly defined in the amended claim, the stent is elastically expandable from a reduced diameter delivery configuration toward a relaxed, resiliently expanded configuration. Additionally, the claim has been amended to reflect that the wall segments, at least at the interrupted sections are preformed to have a relaxed, undeformed and resiliently expanded state in which they project radially outwardly. The radially outward projection is such that when the stent is deployed and expanded in a curved vessel, the wall segments at the interrupted intersections will not project inwardly into the stent lumen. The claim also has been amended to reflect that the stent is deformable to a reduced diameter containable in a delivery device by which the stent and the radially projectable wall segments are resiliently contained so that upon release, the stent and the wall segments will assume their expanded and radially outwardly projecting configurations.

### **THE CITED PRIOR ART**

#### **U.S. Patent 5,514,154 (Lau)**

The Lau patent is directed to a stent having a plurality of radially expandable cylindrical elements, each of which being defined in a somewhat serpentine pattern. Adjacent hoop-like cylindrical elements are connected to each other by interconnecting elements 13. Some of the peaks defined by the serpentine configuration are not associated with interconnecting elements. The serpentine pattern 30 is said to be made up of a plurality of U-shaped members 31, W-shaped members 32 and Y-shaped members 33. The stent is formed from a cylindrical tube by chemical etching. As near as can be determined from Lau, all of the components of the stent, including the U-shaped, W-shaped and Y-shaped members lie in the cylindrical wall of the stent before the stent is expanded. Lau explains, however, that "...during radial expansion U-

shaped members 31 will tip outwardly thereby forming outwardly projecting edges...[that] provide for a roughened outer wall surface of stent 10 and assist in implanting the stent in the vascular wall by embedding into the vascular wall." (Lau 6:19-24). Lau also states that "...any of the U-shaped members 31, W-shaped members 32 and Y-shaped members 33 can tip radially outward to form a projecting edge 34 [, it] is **most likely** and preferred that U-shaped members 31 tip outwardly ...". (6:28-32). (emphasis supplied). Moreover, it is notable that Lau does not explain how any of the members 31, 32 or 33 is caused to tip outwardly. No special steps are suggested during the manufacture of the stent and no particular structure is disclosed other than the specific stent pattern. As near as may be determined from the Lau disclosure, the outward tipping characteristic that results when the stent is expanded appears to be an unexplained phenomenon that occurs with Lau's plastically expandable stent.

#### **European Patent Application 792627A2 (Fogarty)**

Fogarty discloses a stent having a wall thickness between about 0.1 millimeter and 0.5 millimeter.

#### **CLAIM REJECTIONS - 35 U.S.C. §112**

The requirement that the claims "particularly point out and distinctly claim" the invention is met when a person experienced in the field of the invention would understand the scope of the subject matter that is patented when the claim is read in conjunction with the rest of the specification. "If the claims when read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, §112 demands no more." Miles Laboratories, Inc. v. Shandon, 997 F.2d 870, 875, 27 USPQ2d 1123, 1126 (Fed. Cir. 1993); see also Union Pacific Resources Co. v. Chesapeake Energy Corp., 236 F.3d 684, 692, 57 USPQ2d 1293, 1297 (Fed. Cir. 2001); North American Vaccine, Inc. v. American Cyanamid Co., F.3d 1571, 1579, 28 USPQ2d 1333, 1339 (Fed. Cir. 1993); Hybritech, Inc. v. Monoclonal Antibodies, 802

F.2d 1367, 1385, 231 USPQ 81, 94-95 (Fed. Cir. 1986).

Claim 27 has been amended to include the same limitations as claim 1. Additionally, it includes the positive recitation of the stent delivery system in the body of the claim. That amendment, however, is considered to be no more than cosmetic because the element of the stent delivery system was present in the claim before the amendment. Here, again, there is no basis in the action to support the notion that one of ordinary skill would not have understood the scope of the claim. The same is true with respect to claim 29 and the amendment by which "application system" has been changed to --delivery system--. While the choice of language may not have been consistent, the inconsistency was not such that one of ordinary skill would not have understood the scope of the claim. The same applies with respect to claim 30 which has not otherwise been amended.

#### **CLAIM REJECTIONS - 35 U.S.C. §102**

Anticipation under 35 U.S.C. §102 requires that each and every limitation of the claim is disclosed in a single prior art reference, either expressly or inherently. The anticipating reference must disclose the elements in the arrangement called for by the claim. If any limitation of the claim is missing, the reference does not anticipate.

Reconsideration is requested of the rejection of amended claims 1, 3, 8-10 and 27-29 as anticipated by Lau '594. Lau does not disclose a stent having "...wall segments [that] are expanded in the radial direction...such that, upon curvature of the stent along the longitudinal direction, a reduction of the inner lumen due to the wall segments at the interrupted intersections is prevented." Although Lau discloses a longitudinally flexible stent in which some portions of the undulating pattern of the stent "most likely" will "tip outwardly" to project outwardly from the outer surface of the stent to secure the stent to the vessel tissue, that is not the same as avoiding obstruction of the lumen of the stent when the stent is bent. There is nothing in Lau that recognizes the problem with which this aspect of applicant's invention is concerned and there is nothing in Lau to describe an intentional structure designed to reduce the incidence of that problem. It does not necessarily follow that the "outward tipping", which is only said to

serve as a means for embedding the stent in the vascular wall to secure the stent in place, would prevent part of Lau's cylindrical member 12 from projecting into the lumen of the stent when the Lau stent is placed in a curved vessel. Moreover, in Lau, the U-shaped members apparently are caused to tip outwardly only as a consequence of the radial balloon expansion of the stent, not by the stent being formed to have applicant's claimed "radially expanded wall segments". In Lau, any outward tipping of any portion of the stent is a consequence, perhaps originally unintended, of the radial expansion of the stent, not of any design characteristic, such as the stent having applicant's claimed radially expanded wall segments. Certainly, there is nothing in Lau to suggest that when the Lau stent is curved, as when being placed in a curved vessel, its stent components will not project into the stent lumen. Indeed, Lau appears to be less than certain as to the manner in which the device operates. Lau, at most, surmises that the U-shaped members 31 tip outwardly when the stent is expanded. "...it is **most likely** and preferred that U-shaped members 31 tip outwardly since they do not join with any connecting member 13 to prevent them from expanding outwardly." (6:30-33). emphasis supplied).

Lau also fails to disclose a stent having wall segments that are "...preformed to have a relaxed, undeformed and resiliently expanded state in which they project radially outward". Lau does not disclose that the self-expanding stent that also has radially outwardly projectable wall segments that are independently radially self-expandable to an outwardly projecting configuration. In Lau, the stent is not elastically expandable from a compressed reduced diameter and those of its members 31, 32 or 33 that may, possibly, project outwardly, do not do so under the influence of their own resilience.

While Lau recites nitinol titanium superelastic alloy as one of many materials (having diverse characteristics) that may be used to make his stent, Lau does not disclose making a stent having anything corresponding to preformed wall segments as claimed.

**CLAIM REJECTIONS - 35 U.S.C. §103**

Reconsideration is requested of the rejection of claims 4, 5, 11 and 30 as defining subject matter that would have been obvious in view of Lau. These claims include the same limitations discussed above in connection with claim 1. Where Lau fails to suggest those claim limitations, there is no basis for the rejection.

As to the limitations that the action acknowledges are not disclosed in Lau (two-thirds of all intersections being interrupted, aperture widths of maximally 9 millimeters when the stent is expanded, and alloy moieties merely characterizing those claimed features as "...a matter of design choice" is no substitute for evidence.

In cases where a single prior art reference is alleged to render the claimed invention obvious, there must be a sufficient showing of a suggestion or motivation for any modification of the teachings of that reference necessary to reach the claimed invention in order to support the obviousness conclusion. *Sibia Neuroscis, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1356, 55 USPQ2d 1927, 1931(Fed. Cir. 2000); *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582, 37 USPQ2d 1314, 1318(Fed. Cir. 1996). This suggestion or motivation may be derived from the prior art reference itself, from the knowledge of one of ordinary skill in the art, or from the nature of the problem to be solved. *Sibia*, 225 F.3d at 1356, 55 USPQ2d at 1931. *McGinley v. Franklin Sports, Inc.* 262 F.3d 1339, 60 USPQ2d 1001 (Fed. Cir. 2001). The action does not explain any reason for one to have been motivated to modify Lau so that the portions of the stent in Lau would not project into the lumen defined by the stent when the stent is curved or to do so in the manner claimed..

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Claim 7 includes the same limitations of claim 1. Fogarty does not disclose those features of applicant's invention, discussed above, that are missing from Lau. Reconsideration of the rejection of claim 7 is requested.

Respectfully submitted,



Arthur Z. Bookstein  
Reg. No. 22,958,  
KIRKPATRICK & LOCKHART LLP  
75 State Street  
Boston, Massachusetts 02109-1808  
Customer No.: 022832  
Tel: 617-261-3100  
Attorneys for Applicant

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